

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Information Management and Technology

Office of Information Management

Office of Technology and Delivery

Division of Application Services

Effective Date: December 14, 2018

1. Division of Application Services (DCNFABB).

- A. Designs, develops, implements, maintains and operates the Food and Drug Administration (FDA) software applications, Commercial Off-The-Shelf (COTS) software, Information Technology (IT) systems, systems support and maintenance, and their integration as cloud computing, incremental deliveries, and structured governance principles.
- B. Establishes and implements an Enterprise IT Common Component Framework containing modules/services to be shared across FDA information systems and maintains and operates FDA enterprise applications.
- C. Designs, develops, implements, and maintains standards-based electronic IT data systems and repositories with an integrated and interoperable information environment to receive, track, report, analyze, and disseminate knowledge on FDA business/program activities.
- D. Directs the development and implementation of FDA data administration policy standards and procedures to ensure design consistency, including review of work products for compliance with standards.
- E. Partners in the development and implementation of technical specifications and plans for procurement of IT equipment (hardware and software) and support resources required for the integration and operation of FDA software applications.
- F. Develops and implements a program risk management plan to oversee and mitigate critical risks and vulnerabilities in the execution of the IT systems.

- G. Partners with IT Senior Leadership in the development and maintenance of FDA's policies and procedures for independent verification and validation of IT systems.
- H. Provides oversight for problem management processes for the FDA applications.

2. Applications Management Services Staff (DCNFABB1).

- A. Establishes and implements an Enterprise IT Common Component Framework for use in application design, development, testing, implementation, operation, and maintenance of FDA applications.
- B. Validates requirements and performs systems analyses to develop and implement quality assurance and testing strategies, procedures and methodologies, especially automated varieties
- C. Develops and implements system specifications, requirements, procedures and guidelines related to software quality assurance and testing.
- D. Supports FDA through effective evaluation and creation of streamlined application development methodologies, monitoring, testing, and integration of application technologies utilizing interchangeable common components to support FDA business process needs and objectives efficiently and effectively.
- E. Develops and implements a program risk management plan to oversee and mitigate critical risks and vulnerabilities in the execution of the systems under its responsibility.
- F. Interfaces with and supports the Division's project management personnel on standards and implementation processes.
- G. Develops, implements, and provides problem management processes for FDA
- H. applications, including trend analysis of problems experienced.
- I. Provides general operational support including asset management, budget control and administrative services in support of this Division.
- J. Develops, implements and manages system specifications, requirements, procedures and guidelines related to software license management including acquisition strategy, procurement, usage reporting and alternative analysis.

3. Data Management and Operations Branch (DCNFABB2).

- A. Designs, develops, implements, maintains and operates standards-based electronic IT data systems and repositories that provide the FDA with an integrated and interoperable information environment.

- B. Directs the development and implementation of FDA data administration policies, standards and procedures to ensure design consistencies, including review of work products for compliance with standards.
- C. Partners in the development and implementation of technical specifications and plans for procurement of IT equipment (hardware and software) and support resources required for the integration and operation of FDA software applications.
- D. Provides oversight for problem management processes for FDA applications, including trend analysis of problems experienced.

4. Medical Products Branch (DCNFABB3).

- A. Designs, develops, implements, maintains and operates Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), and Center for Devices and Radiological Health (CDRH) software applications, COTS, Information Technology (IT) systems, systems support and maintenance, and their integration with other Federal agencies, state and foreign governments; and public and private entities by utilizing Office of Management and Budget (OMB) sanctioned plans such as cloud computing, incremental deliveries, and structured governance principles.
- B. Validates requirements and directs the design, development and implementation of new system requirements, system enhancements and system maintenance changes for the FDA, performs systems analyses to develop and implement testing strategies, procedures and methodologies, especially automated varieties, and develops and implements system specifications, requirements, procedures and guidelines.
- C. Partners in the development and implementation of technical specifications and plans for procurement of IT equipment (hardware and software) and support resources required for the integration and operation of FDA software applications.

5. OC/CVM/CTP Branch (DCNFABB4)

- A. Designs, develops, implements, maintains and operates all Office of the Commissioner (OC), Center for Tobacco Products (CTP), and Center for Veterinary Medicine (CVM) software applications, COTS, IT systems, systems support and maintenance, and their integration with other Federal agencies, state and foreign governments; and public and private entities by utilizing OMB sanctioned plans such as cloud computing, incremental deliveries, and structured governance principles.

- B. Validates requirements for and directs the design, development and implementation of new system requirements, system enhancements and system maintenance changes for the FDA, performs systems analyses to develop and implement testing strategies, procedures and methodologies, especially automated varieties, and develops and implements system specifications, requirements, procedures and guidelines.
- C. Partners in the development and implementation of technical specifications and plans for procurement of IT equipment (hardware and software) and support resources required for the integration and operation of FDA software applications.

6. ORA/CFSAN Branch (DCNFABB5)

- A. Designs, develops, implements, maintains, operates the Office of Regulatory Affairs (ORA) and the Center for Food Safety and Applied Nutrition (CFSAN) software applications, COTS, Information Technology (IT) systems, systems support and maintenance, and their integration with other Federal agencies, state and foreign governments; and public and private entities by utilizing OMB sanctioned plans such as cloud computing, incremental deliveries, and structured governance principles.
- B. Validates requirements and directs the design, development and implementation of new system requirements, system enhancements and system maintenance changes for the FDA, performs systems analyses to develop and implement testing strategies, procedures and methodologies, especially automated varieties, and develops and implements system specifications, requirements, procedures and guidelines.
- C. Partners in the development and implementation of technical specifications and plans for procurement of IT equipment (hardware and software) and support resources required for the integration and operation of FDA software applications.

7. Enterprise Application Branch (DCNFABB6)

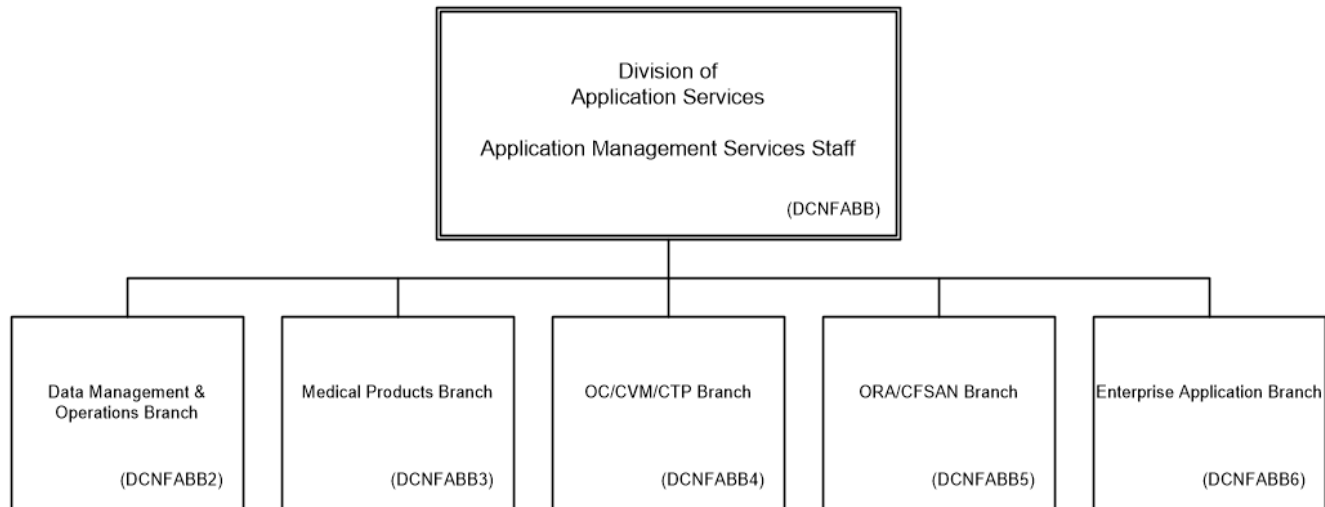
- A. Designs, develops, implements, maintains, operates the FDA-wide software applications, COTS, Information Technology (IT) systems, systems support and maintenance, and their integration with other federal agencies, state and foreign governments; and public and private entities by utilizing OMB sanctioned plans such as cloud computing, incremental deliveries, and structured governance principles.

- B. Validates requirements and directs the design, development and implementation of new system requirements, system enhancements and system maintenance changes for the OC and FDA-wide applications, performs systems analyses to develop and implement testing strategies, procedures and methodologies, especially automated varieties, and develops and implements system specifications, requirements, procedures and guidelines.
- C. Partners in the development and implementation of technical specifications and plans for procurement of IT equipment (hardware and software) and support resources required for the integration and operation of FDA software applications.

8. Authority and Effective Date.

The functional statements for the Division of Application Services were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
Food and Drug Administration
Office of Operations
Office of Information Management and Technology
Office of Information Management
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Division of Application Services**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Operations, Office of Information Management and Technology, Office of Information Management, Office of Technology and Delivery, Division of Application Services organization structure depicting all the organizational structures reporting to the Director.

These organizations below report to the Division of Application Services (DCNFABB)

Application Management Services Staff
Data Management and Operations Branch (DCNFABB2)
Medical Products Branch (DCNFABB3)
OC/CVM/CTP Branch (DCNFABB4)
ORA/CFSAN Branch (DCNFABB5)
Enterprise Application Branch (DCNFABB6)